December 3, 1999
The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

9341 '99 DEC 22 A9:51

Re: 21 CFR Parts 210,211, 820, and 1271
Suitability Determination for Donors of Human Cellular & Tissue-Based Products

To Whom It May Concern:

As a member of Lions Club in South Florida, I am writing to express my opposition to the proposed Food and Drug Administration's rule to require a donor medical history interview for all corneal donors. I am proud of the fact that the Florida Lions Eye Bank has, over the past 38 years, provided more then 32,000 corneas and 3,000 scleras to patients totally free of charge. This has saved the Medicare program more than $1,000,000 each year in recent years.

I understand that this proposed rule is an effort on the part of the FDA to prevent the spread of communicable diseases such as Creuzfeldt Jakob Disease (CJD). However, I do not believe that the requirement will serve that purpose. Many next of kin do not have the necessary information needed to determine donor suitability. To try to locate the next of kin or even someone else who may be "knowledgeable about the donor's medical history and relevant social behavior" would both delay and impede the time-limited process of obtaining surgical quality corneas for patients here in South Florida.

As you must know, most medical examiner cases from which surgical quality corneas might be taken are those in the 20 -40 year age range. Also, those who die a sudden death from other causes, but who might have the disease in the latent stage, would not exhibit any symptoms of CJD.. . thus asking even hundreds of questions regarding behavior, etc would serve no purpose.

Each day here in South Florida new patients are added to the waiting list for corneal transplantation. Unnecessary screening will further delay the wait time and extend the suffering and impaired vision of many men, women, and children. In addition, if the eye bank is forced to hire more employees to try to track down someone to interview on each suitable case at the medical examiner's offices, it will become necessary to begin to charge a processing fee. Since the majority of corneal and scleral recipients are over 65, the government will be charged for a service provided free for 38 years.

Sincerely, Don K. Davenport

Don K. Davenport — Avon Park, FL 33825
Name (Printed) — Lions Club Membership

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97N-484 (over) C154

12-15-99

Gentlemen,

Quite frankly, if its not broken why try to fix it?

This appears to be a very costly proposal to protect recipients of transplants that is totally unnecessary.

The Lions have provided this service free of cost to those in need for many years. Its wonderful to provide sight to those in need and at a tremendous savings to all the people.

Please do not adopt the proposed regulation and handicap those already in need and add an additional burden to the taxpayers.

It appears that someone will profit, not those in need, from passage of this unnecessary regulation.

Its time to practice some statesmanship!

Llon K. Davenport

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